

JS 44 (Rev. 12/07)

**CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**

Alzheimer's Institute of America, Inc.

(b) County of Residence of First Listed Plaintiff Wyandotte (KS)  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Fox Rothschild LLP, 2000 Market Street, 20th Floor, Phila, PA  
19103 (215-299-2854)

**DEFENDANTS**

Avid Radiopharmaceuticals, Inc. and The Trustees of The University of Pennsylvania

County of Residence of First Listed Defendant Philadelphia (PA)  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE  
LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition		

**V. ORIGIN**

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

35 U.S.C. § 284Brief description of cause:  
Patent Infringement**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

**DEMANDS**damages / injunctive rel.

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

11/24/2010

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

Alzheimer's Institute

of America, Inc.

v.

Avid Radiopharmaceuticals, Inc.

Trustees of the Univ. of Penn.

:  
:  
:  
:  
:

CIVIL ACTION

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

<u>11/24/2010</u>	<u>Peter C. Buckley</u>	<u>Plaintiff</u>
<b>Date</b>	<b>Attorney-at-law</b>	<b>Attorney for</b>
<u>215-299-2854</u>	<u>215-299-2150</u>	<u>pbuckley@foxrothschild.com</u>
<b>Telephone</b>	<b>FAX Number</b>	<b>E-Mail Address</b>

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

ALZHEIMER'S INSTITUTE OF  
AMERICA, INC.,  
7837 Parallel Parkway  
Kansas City, Kansas 66112,

Plaintiff,

v.

AVID RADIOPHARMACEUTICALS,  
3711 Market Street, 7<sup>th</sup> Floor  
Philadelphia, Pennsylvania 19104,

and

THE TRUSTEES OF THE  
UNIVERSITY OF PENNSYLVANIA,  
3451 Walnut Street  
Philadelphia, Pennsylvania 19104,

Defendants.

Case No.

**DEMAND FOR JURY TRIAL**

**COMPLAINT FOR DAMAGES AND  
INFRINGEMENT**

**PLAINTIFF'S COMPLAINT**

COMES NOW plaintiff Alzheimer's Institute of America, Inc. ("AIA"), by and through its attorneys, and for its Complaint against defendants Avid Radiopharmaceuticals, Inc. ("Avid") and The Trustees of the University of Pennsylvania ("University of Pennsylvania") (collectively, "Defendants"), states as follows:

**Nature of the Action**

1. This Complaint seeks a judgment finding that Defendants have infringed and continue to infringe upon AIA's U.S. Patent Nos. 5,455,169 (the "'169 Patent'"), and 7,538,258 (the "'258 Patent'") (collectively, the "Patents-in-Suit"). The Patents-in-Suit cover a wide range of Alzheimer's disease-related technology, including, but not limited to: nucleic acids coding for the Swedish mutation and transgenic mice expressing the Swedish mutation containing nucleic acids. Mice containing nucleic acid encoding for the Swedish mutation, including Tg2576 mice and APPswe-PSEN1 mice, are covered by the '169 Patent and the '258 Patent. The claimed

technology provides important insights and tools for Alzheimer's disease research. True and accurate copies of the Patents-in-Suit are attached hereto, respectively, as Exhibits A and B.

### **Jurisdiction and Venue**

2. This Court has subject matter jurisdiction over this Complaint pursuant to 28 U.S.C. §§ 1331 and 1338(a), and under the patent laws of the United States pursuant to 35 U.S.C. § 1, *et seq.*

3. Venue is proper in this judicial district under the provisions of 28 U.S.C. §§ 1391(b) and 1400(b).

### **The Parties**

4. AIA is a corporation organized and existing under the laws of Florida and having its principal place of business at 7837 Parallel Parkway, Kansas City, Kansas 66112. AIA is the owner of the Patents-in-Suit.

5. Avid is a Pennsylvania corporation having its principal place of business at 3711 Market Street, 7<sup>th</sup> Floor, Philadelphia, Pennsylvania 19104. Avid has committed acts of patent infringement in this district.

6. The University of Pennsylvania is a private non-profit institution having its principal place of business at the University of Pennsylvania, 3451 Walnut Street, Philadelphia, Pennsylvania 19104. The University of Pennsylvania has committed acts of patent infringement in this district.

### **Facts**

7. Approximately 5 million people nationwide currently suffer from Alzheimer's disease. Alzheimer's disease is a neurodegenerative disease whose symptoms include memory loss, disorientation, and dementia. Alzheimer's disease is fatal.

8. Alzheimer's disease is characterized by the accumulation of aggregated A $\beta$  or  $\beta$ -Amyloid peptides in senile plaques and vascular deposits.

9. AIA's patents cover a wide range of Alzheimer's disease-related technology, including, nucleic acids coding for the Swedish mutation. The Swedish mutation is a genetic mutation that results in increased amounts of  $\beta$ -Amyloid plaques. The Swedish mutation is used to model the effects of Alzheimer's disease for *in vitro*, *in vivo*, and animal testing.

10. Alzheimer's disease is currently diagnosed using clinical criteria, which are often inaccurate and are useful only late in the disease progression. While definitive diagnosis requires identification of amyloid plaques in the brain at autopsy, there is increasing evidence that amyloid plaques are present for many years prior to the onset of dementia.

11. Early and accurate detection of amyloid plaques by brain imaging could provide an opportunity to dramatically improve diagnosis of Alzheimer's disease and could allow monitoring of disease progression. An agent that would allow amyloid plaques to be imaged is, thus, of great commercial and medical value – both for diagnostic and drug development purposes.

12. Upon information and belief, the University of Pennsylvania was aware of the vast commercial value that such an amyloid imaging agent would have. University of Pennsylvania researchers Daniel M. Kovronsky, Bin Zhang, Mei-Ping Kung, Hank F. Kung, John Q. Trojanowski, and Virginia M-Y. Lee led the University of Pennsylvania's initial efforts to develop an amyloid imaging agent. Dr. Daniel M. Skovronsky served as Scientific Director of High Throughput Screening and Drug Discovery at the Center for Neurodegenerative Disease Research at the University of Pennsylvania. Dr. Hank F. Kung served as served as Professor of Radiology and Pharmacology.

13. On June 20, 2000, the University of Pennsylvania published the results of its "first step" towards the development of such an amyloid imaging agent in the *Proceedings for National Academy of Sciences*, Vol. 97, No. 13, pp. 7609-7614 (June 20, 2000). As described in the publication, the University of Pennsylvania developed a fluorescent probe known as [(trans, trans)-1-bromo-2,5-bis-(3-hydroxycarbonyl-4-hydroxy)styryl]benzene or "BSB" for short. Prior to this publication entitled, "*In vivo* detection of amyloid plaques in a mouse model of

Alzheimer's disease," no probe had been shown to label senile or amyloid plaques *in vivo*, which is required of a ligand used for imaging plaques in Alzheimer's disease patients.

14. To determine whether BSB could label amyloid plaques *in vivo*, the University of Pennsylvania used a transgenic mouse strain known as Tg2576. The Tg2576 mouse contains nucleic acids encoding for amyloid precursor protein with the Swedish mutation. Due to the presence of the Swedish mutation, the Tg2576 mice over produce  $\beta$ -Amyloid, develop  $\beta$ -Amyloid plaques, and demonstrate symptoms consistent with Alzheimer's disease. Because the Tg2576 mice contain nucleic acids encoding for amyloid precursor protein with the Swedish mutation, a license from AIA is required to use the Tg2576 mice. Without a license, use of the Tg2576 mice is an infringement of the '169 Patent and the '258 Patent.

15. The University of Pennsylvania was not authorized to use the Tg2576 mice for profit-making or commercial purposes. The University of Pennsylvania understood that its use of the Tg2576 mice in developing an amyloid imaging agent was a commercial purpose.

16. As a direct result of its use of the Tg2576 mice, the University of Pennsylvania concluded that "BSB is an appropriate starting point for future efforts to generate an antemortem diagnostic for AD [Alzheimer's disease]" and that "BSB can serve as a useful prototype ligand for developing probes to establish a diagnosis of AD in living patients." In particular, the University of Pennsylvania determined that "BSB has several properties that suggest that BSB or a BSB-like derivative may become a useful probe for imaging AD pathology *in vivo*: (i) BSB labels A $\beta$  amyloid plaques specifically and sensitively; (ii) BSB is cell permeable; (iii) BSB distributes through the brain after a single intracerebral injection; (iv) after binding to plaques, BSB is stable *in vivo*; and (v) BSB cross the BBB [blood brain barrier] of transgenic mouse models of AD amyloidosis and labels A $\beta$  deposits."

17. Between 2000 and 2005, the University of Pennsylvania continued to use the Tg2576 mice to identify, validate, and test potential amyloid imaging agents. For example, in June 2002, the University of Pennsylvania described the use of the Tg2576 mice in testing of compounds known as [ $^{125}$ I]IMSB and [ $^{125}$ I]TZDM, which showed a 10-fold greater brain



penetration compared to BSB. In addition, these radiolabeled probes labeled plaques with higher sensitivity for *in vivo* imaging in contrast to fluorescent probes like BSB, which require exposure of the brain to microscopy.<sup>1</sup> Radiolabeled probes may be imaged using positron emission computed tomography (PET) or single photon emission computed tomography (SPECT) imaging. In addition, the University of Pennsylvania used Tg2576 mice to identify and validate the radiolabeled compound known as [<sup>125</sup>I]IMPY as a potential amyloid imaging agent.<sup>2</sup>

18. In late 2004, Dr. Skovronsky and Dr. Kung founded defendant Avid. Upon information and belief, Avid was designed to commercialize and monetize the discoveries made at the University of Pennsylvania. Dr. Skovronsky is the CEO and a shareholder of Avid. Dr. Kung is a scientific advisor and shareholder of Avid. Avid licensed certain technology from the University of Pennsylvania that was discovered by using AIA's patented technology.

19. According to its website, "Avid's Alzheimer's disease program is based on the hypothesis that *in vivo* detection of amyloid plaques by positron emission computed tomography (PET) or single photon emission computed tomography (SPECT) imaging will be useful as biomarkers for monitoring and diagnosis of Alzheimer's disease. In collaboration with Dr. Hank Kung at the University of Pennsylvania, we have developed novel radiolabeled compounds that specifically and sensitively bind  $\beta$ -amyloid (the chief constituent of amyloid plaques) and are testing these compounds as molecular imaging agents in preclinical and clinical trials."

20. Since Avid's founding, Avid and the University of Pennsylvania have collaborated in the identification, validation, testing, and commercialization of amyloid imaging agents.<sup>3</sup> The collaboration between Avid and the University of Pennsylvania included the

<sup>1</sup> See M.-P. Kung, et al., "Detection of Amyloid Plaques by Radioligands for A $\beta$ 40 and A $\beta$ 42," *Journal of Molecular Neuroscience*, Vol. 20, pp. 15-23 (2003).

<sup>2</sup> See H.F. Kung, et al., "Iodinated Tracers for Imaging Amyloid Plaques in the Brain," *Molecular Imaging and Biology*, Vol. 5, No. 6, pp. 418-426 (2003).

<sup>3</sup> See, e.g., A. B. Newberg, et al., "Safety, Biodistribution, and Dosimetry of <sup>123</sup>I-IMPY: A Novel Amyloid Plaque-Imaging Agent for the Diagnosis of Alzheimer's Disease," *The Journal of Nuclear Medicine*, Vol. 47, No. 5, pp. 748-754 (May 2006); C. C. Rowe, et al., "Imaging of amyloid  $\beta$  in Alzheimer's disease with <sup>18</sup>F-BAY94-9172, a novel PET tracer: proof of mechanism," *The Lancet: Neurology*, Vol. 7, pp. 129-135 (February 2008); W. Qu, et al.,

continued use of the Tg2576 mice and other mice containing nucleic acids encoding for amyloid precursor protein with the Swedish mutation.

21. For example, in C. C. Rowe, et al., “Imaging of amyloid  $\beta$  in Alzheimer’s disease with  $^{18}\text{F}$ -BAY94-9172, a novel PET tracer: proof of mechanism,” *The Lancet: Neurology*, Vol. 7, pp. 129-135 (February 2008), Avid and the University of Pennsylvania report that “[a]fter injection into Tg2576 transgenic mice, *ex vivo* brain sections showed localization of  $^{18}\text{F}$ -BAY94-9172 in regions with A $\beta$  plaques as confirmed by thoflavin binding.”

22. In November 2009, Avid and the University of Pennsylvania jointly reported on the properties of an amyloid imaging agent known as  $^{18}\text{F}$ -AV-45. See S.R. Choi, et al., “Preclinical Properties of  $^{18}\text{F}$ -AV-45: A PET Agent for A $\beta$  Plaques in the Brain,” *The Journal of Nuclear Medicine*, Vol. 50, No. 11, pp. 1887-1894 (November 2009). In particular, they reported that “ $^{18}\text{F}$ -AV-45 displayed excellent binding affinity to A $\beta$  plaques in the AD brain by *ex vivo* autoradiography in transgenic AD model mice.” The transgenic AD model mice used by Avid and the University of Pennsylvania included mice known as B6 Cg-Tg APPswe-PSEN1.

23. According to the publication, Avid and the University of Pennsylvania purchased the B6 Cg-Tg APPswe-PSEN1 mice from The Jackson Laboratory. The Jackson Laboratory sells these APPswe-PSEN1 mice as stock number 004462. The APPswe-PSEN1 mice infringe the Patents-in-Suit. The sale of the APPswe-PSEN1 mice was not authorized by AIA. The use of the APPswe-PSEN1 mice by Avid and the University of Pennsylvania was not authorized by

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“Synthesis and evaluation of indoliny- and indolylphenylacetylenes as PET imaging agents for  $\beta$ -amyloid plaques,” *Bioorg. Med. Chem. Lett.*, Vol. 18, No. 17, pp. 4823-4827 (September 2008); S.-P. Wey, et al., “Validation of an  $^{18}\text{F}$ -labeled biphenylalkyne as a positron emission tomography imaging agent for  $\beta$ -amyloid plaques,” *Nuclear Medicine and Biology*, Vol. 36, pp. 411-417 (2009); H. F. Kung, et al., “ $^{18}\text{F}$  Stilbenes and Styrylpyridines for PET Imaging of A $\beta$  Plaques in Alzheimer’s Disease: A Miniperspective,” *Journal of Medicinal Chemistry*, Vol. 53, No. 3, pp. 933-941 (2010); C.-H. Yao, et al., “GMP-compliant automated synthesis of [ $^{18}\text{F}$ ]AV-45 (Florbetapir F 18) for imaging  $\beta$ -amyloid plaques in human brain,” *Applied Radiation and Isotopes*, Vol. 68, pp. 2293-2297 (2010); D. F. Wong, et al., “In Vivo Imaging of Amyloid Deposition in Alzheimer Disease Using the Radioligand  $^{18}\text{F}$ -AV-45 (Florbetapir F 18),” *The Journal of Nuclear Medicine*, Vol. 51, No. 6, pp. 913-920 (June 2010); K.-J. Lin, et al., “Whole-body biodistribution and brain PET imaging with [ $^{18}\text{F}$ ]AV-45, a novel amyloid imaging agent – a pilot study,” *Nuclear Medicine and Biology*, Vol. 37, pp. 497-508 (2010).



AIA. Without a license, use of the APPswe-PSEN1 mice is an infringement of the '169 Patent and the '258 Patent.

24. The Jackson Laboratory prominently announces on its website and in the Terms of Use it sends with the APPswe-PSEN1 mice that the APPswe-PSEN1 strain of mice is “not available to companies or for-profit entities” and that “use of these MICE for Commercial Purposes is strictly prohibited.” Avid and the University of Pennsylvania knew or should have known that the commercial use of the APPswe-PSEN1 mice was not authorized.

25. Defendant Avid describes itself as “a pioneer in the development of agents for diagnosis of Alzheimer’s disease.” According to its website, Avid “has developed proprietary targeting agents to image  $\beta$ -Amyloid plaques and is currently testing these compounds in clinical trials for the detection of Alzheimer’s disease.” One such imaging agent,  $^{18}\text{F}$ -AV-45, is currently in Phase III clinical trials as part of the FDA approval process.

26. The imaging agents that Avid and the University of Pennsylvania have identified, validated, and tested using AIA’s patented technology are extremely valuable. The University of Pennsylvania has filed applications for, and obtained, patents with the United States Patent and Trademark Office, including U.S. Patent Nos. 6,696,039; 6,946,116; 7,250,525; 7,297,820; 7,425,318; 7,678,819; 7,687,052; 7,759,502; and 7,807,135, in which the University of Pennsylvania claims certain amyloid imaging agents that were identified, validated, and tested using AIA’s patented technology. The University of Pennsylvania has licensed certain of these applications and patents to Avid.

27. According to its website, Avid has raised at least \$69.5 million dollars in financing since 2006. In addition, Avid has entered into an exclusive option agreement with Bayer Schering Pharma for the development of certain of these amyloid imaging agents, including  $^{18}\text{F}$ -BAY94-9172.

28. In April 2010, Avid reported positive interim results from the Phase III clinical trial of its amyloid imaging agent Florbetapir F18, also known as  $^{18}\text{F}$ -AV-45, stating that the

“early data show strong correlation between Florbetapir PET imaging and Alzheimer’s disease beta-amyloid pathology as assessed at autopsy.”

29. As of October 2010, Avid has completed its Phase III study on Florebetapir F18.

30. On November 8, 2010, Eli Lilly and Company (“Lilly”) announced that it had signed a definitive merger agreement to acquire Avid. Lilly stated that “Avid’s lead program in development is Florbetapir F 18 (<sup>18</sup>F-AV-45), a molecular imaging agent under investigation for detecting the presence of amyloid plaque in the brain. Beta-amyloid plaque is a defining pathology of Alzheimer’s disease. A marketing application for Florbetapir has recently been submitted to the U.S. Food and Drug Administration (FDA).” According to Lilly’s press release, Lilly will acquire all outstanding shares of Avid for an upfront payment of \$300 million, subject to adjustment based on existing cash on hand at closing. In addition, Avid shareholders, including Dr. Skovronsky and Dr. Kung, will also be eligible for up to \$500 million in additional payments contingent upon potential future regulatory and commercial milestones for Florbetapir.

31. On November 17, 2010, AIA sent a letter to Defendants informing Defendants that AIA believed Defendants were infringing on AIA’s patented technology. AIA requested that Defendants provide AIA with the legal basis for their prior and apparent continuing use of AIA’s patents. Defendants’ deadline to respond to the letter was November 24, 2010. As of the filing of this Complaint, AIA had not received a response from Defendants.

## **COUNT I**

### **Patent Infringement of U.S. Patent No. 5,455,169**

32. AIA incorporates by reference each and every allegation set forth in paragraphs 1 through 31 of its Complaint as if fully set forth and restated herein.

33. The ‘169 Patent entitled “Nucleic acids for diagnosing and modeling Alzheimer’s disease” was duly and regularly issued on October 3, 1995. AIA is the sole and exclusive owner of the ‘169 Patent. At all relevant times, the owner of the ‘169 Patent has complied with 35 U.S.C. § 287(a).

34. Defendants, without the authority or consent of AIA, have used in the United States, including, but not limited to, in this judicial district, technologies which infringe upon the '169 Patent. Upon information and belief, Defendants' infringement of the '169 Patent is knowing and willful.

35. Avid's and the University of Pennsylvania's infringement of the '169 Patent has caused and continues to cause damage to AIA. Among other remedies, AIA is entitled to a reasonable royalty that includes a percentage of the expected sales of Florbetapir and other compounds that were identified, validated, and tested using AIA's patented technology.

## **COUNT II**

### **Patent Infringement of U.S. Patent No. 7,538,258**

36. AIA incorporates by reference each and every allegation set forth in paragraphs 1 through 35 of its Complaint as if fully set forth and restated herein.

37. The '258 Patent entitled "Transgenic mouse expressing an APP 670/671 mutation" was duly and regularly issued on May 26, 2009. AIA is the sole and exclusive owner of the '258 Patent. At all relevant times, the owner of the '258 Patent has complied with 35 U.S.C. § 287(a).

38. Defendants, without the authority or consent of AIA, have used in the United States, including, but not limited to, in this judicial district, technologies which infringe upon the '258 Patent. Upon information and belief, Defendants' infringement of the '258 Patent is knowing and willful.

39. Avid's and the University of Pennsylvania's infringement of the '258 Patent has caused and continues to cause damage to AIA. Among other remedies, AIA is entitled to a reasonable royalty that includes a percentage of the expected sales of Florbetapir and other compounds that were identified, validated, and tested using AIA's patented technology.

## **PRAYER**

WHEREFORE, plaintiff Alzheimer's Institute of America respectfully prays that the Court enter judgment in its favor and award the following relief against Defendants:

- A. Find that Defendants infringed upon the Patents-in-Suit;
- B. Find that the infringement of Defendants upon the Patents-in-Suit was knowing and willful;
- C. Enjoin Defendants and their respective officers, directors, employees, agents, licensees, representatives, affiliates, related companies, servants, successors and assigns, and any and all persons acting in privity or in concert with any of them, preliminarily and permanently, from further infringing upon the Patents-in-Suit;
- D. Order that an accounting be made to establish damages arising out of Defendants' infringement of the Patents-in-Suit;
- E. Award AIA actual damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial as a result of Defendants' infringement upon the Patents-in-Suit;
- F. Award AIA treble damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial as a result of Defendants' knowing and willful infringement upon the Patents-in-Suit;
- G. Award AIA its costs and reasonable attorneys' fees incurred in connection with this action; and
- H. Award and grant AIA such other and further relief as the Court deems just and proper under the circumstances.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a jury trial.

Dated: November 24, 2010

**FOX ROTHSCHILD LLP**

By: 

Abraham C. Reich (I.D. No. 20060)  
Peter C. Buckley (I.D. No. 93123)(pcb8931)  
Fox Rothschild LLP  
2000 Market Street, 20<sup>th</sup> Floor  
Philadelphia, PA 19103  
215-299-2854 (phone)  
215-299-2150 (fax)  
[areich@foxrothschild.com](mailto:areich@foxrothschild.com)  
[pbuckley@foxrothschild.com](mailto:pbuckley@foxrothschild.com)

Attorneys for Plaintiff,  
Alzheimer's Institute of America, Inc.

Of Counsel:

K. Lee Marshall, Esquire  
Ameer Gado, Esquire  
Deborah Goldfarb, Esquire  
BRYAN CAVE LLP  
Two Embarcadero Center  
Suite 1410  
San Francisco, CA 94111  
415-675-3400 (phone)  
415-675-3434 (fax)  
[klmarshall@bryancave.com](mailto:klmarshall@bryancave.com)  
[aagado@bryancave.com](mailto:aagado@bryancave.com)  
[Deborah.goldfarb@bryancave.com](mailto:Deborah.goldfarb@bryancave.com)